Atty. Dkt. No. 029318-0615 Appln. Ser. No. 09/597,738

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

- 1. 50. (Cancelled).
- 51. (Currently amended) An aerosol composition of an aqueous dispersion of nanoparticulate drug particles <u>suitable for administration of a drug dosage in less than</u> about 15 seconds, wherein:
 - (a) essentially each droplet of the aerosol comprises at least one nanoparticulate drug particle, wherein
 - (i) the drug has a solubility in said aqueous dispersion of less than about 10 mg/mL;
 - (ii) the drug is selected from the group consisting of, naproxen, triamcinolone acetonide, budesonide, and an anti-emetic; and
 - (iii) the drug is present in a concentration of from about 0.05 mg/mL up to about 600 mg/mL;
 - (b) the droplets of the aerosol have a mass median aerodynamic diameter (MMAD) less than or equal to about 100 microns; and
 - (c) the nanoparticulate drug particles eomprise a poorly soluble drug, have an effective average particle size of less than about 1000 nm, and have a surface modifier adsorbed on the surface of the drug.
- 52. (Currently Amended) The aerosol composition of claim 51, wherein the <u>composition</u> is suitable for administration of a drug dosage in about 1 to 2 seconds drug is selected from the group consisting of proteins, peptides, bronchodilators, corticosteroids, elastase inhibitors, analgesics, anti-fungals, cystic-fibrosis therapies, asthma therapies, emphysema therapies, respiratory distress syndrome therapies, chronic bronchitis therapies, chronic



obstructive pulmonary disease therapies, organ-transplant rejection therapies, therapies for tuberculosis and other infections of the lung, fungal infection therapies, respiratory illness therapies associated with acquired immune deficiency syndrome, an oncology drug, an antiemetic, an analgesic, and a cardiovascular agent.

- 53. (Previously presented) The aerosol composition of claim 51, wherein the nanoparticulate drug particles have an effective average particle size of less than about 400 nm.
- 54. (Previously presented) The aerosol composition of claim 51, wherein the nanoparticulate drug particles have an effective average particle size of less than about 300 nm.
- 55. (Previously presented) The aerosol composition of claim 51, wherein the nanoparticulate drug particles have an effective average particle size of less than about 250 nm.
- 56. (Previously presented) The aerosol composition of claim 51, wherein the nanoparticulate drug particles have an effective average particle size of less than about 100 nm.
- 57. (Previously presented) The aerosol composition of claim 51, wherein the nanoparticulate drug particles have an effective average particle size of less than about 50 nm.
- 58. (Cancelled)
- 59. (Currently amended) The aerosol composition of claim [[58]] <u>51</u>, wherein the aerosol comprises a concentration of a drug selected from the group consisting of about 10 mg/mL or more, about 100 mg/mL or more, about 200 mg/mL or more, about 400 mg/mL or more, and about 600 mg/mL.
- 60. (Previously presented) The aerosol composition of claim 51, wherein the droplets of the aerosol have a mass median aerodynamic diameter (MMAD) of about 2 to about 10 microns.



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- 61. (Previously presented) The aerosol composition of claim 60, wherein the droplets of the aerosol have a mass median aerodynamic diameter (MMAD) of from about 2 to about 6 microns.
- 62. (Previously presented) The aerosol composition of claim 51, wherein the droplets of the aerosol have a mass median aerodynamic diameter (MMAD) of less than about 2 microns.
- 63. (Previously presented) The aerosol composition of claim 51, wherein the droplets of the aerosol have a mass median aerodynamic diameter (MMAD) of about 5 to about 100 microns.
- 64. (Previously presented) The aerosol composition of claim 63, wherein the droplets of the aerosol have a mass median aerodynamic diameter (MMAD) of about 30 to about 60 microns.
- 65. 78. (Cancelled).
- 79. (Currently amended) A method of administering to a patient the an aerosol of claim 51 to a patient composition of an aqueous dispersion of nanoparticulate drug particles, wherein[[:]] the aerosol comprises drug at a concentration of 10 mg/mL or greater,
 - (a) essentially each droplet of the aerosol comprises at least one nanoparticulate drug particle, wherein
 - (i) the drug has a solubility in said aqueous dispersion of less than about 10 mg/mL;
 - (ii) the drug is selected from the group consisting of naproxen, triamcinolone acetonide, budesonide, and an anti-emetic; and
 - (iii) the drug is present in a concentration from about 0.05 mg/mL up to about 600 mg/mL;
 - (b) the droplets of the aerosol have a mass median aerodynamic diameter
 (MMAD) less than or equal to about 100 microns; and



(c) the nanoparticulate drug particles have an effective average particle size of less than about 1000 nm, and have a surface modifier adsorbed on the surface of the drug;

and wherein the patient delivery time for the aerosol administration is about 15 seconds or less.

- 80. (Previously presented) The aerosol composition of claim 51, wherein at least 70% of the drug particles have a particle size of less than about 1000 nm.
- 81. (Previously presented) The aerosol composition of claim 51, wherein at least 90% of the drug particles have a particle size of less than about 1000 nm.
- 82. 119. (Cancelled)
- 120. (New) The method of claim 79, wherein the patient delivery time for the aerosol administration is about 1 to 2 seconds.
- 121. (New) The method of claim 79, wherein the nanoparticulate drug particles have an effective average particle size of less than about 400 nm.
- 122. (New) The method of claim 79, wherein the nanoparticulate drug particles have an effective average particle size of less than about 300 nm.
- 123. (New) The method of claim 79, wherein the nanoparticulate drug particles have an effective average particle size of less than about 250 nm.
- 124. (New) The method of claim 79, wherein the nanoparticulate drug particles have an effective average particle size of less than about 100 nm.
- 125. (New) The method of claim 79, wherein the nanoparticulate drug particles have an effective average particle size of less than about 50 nm.



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- 126. (New) The method of claim 79, wherein the aerosol comprises a concentration of a drug selected from the group consisting of about 10 mg/mL or more, about 100 mg/mL or more, about 200 mg/mL or more, about 400 mg/mL or more, and about 600 mg/mL.
- 127. (New) The method of claim 79, wherein the droplets of the aerosol have a mass median aerodynamic diameter (MMAD) of about 2 to about 10 microns.
- 128. (New) The method of claim 127, wherein the droplets of the aerosol have a mass median aerodynamic diameter (MMAD) of from about 2 to about 6 microns.
- 129. (New) The method of claim 79, wherein the droplets of the aerosol have a mass median aerodynamic diameter (MMAD) of less than about 2 microns.
- 130. (New) The method of claim 79, wherein the droplets of the aerosol have a mass median aerodynamic diameter (MMAD) of about 5 to about 100 microns.
- 131. (New) The method of claim 130, wherein the droplets of the aerosol have a mass median aerodynamic diameter (MMAD) of about 30 to about 60 microns.